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The EU Cosmetics Regulation

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Topics

- General EU Market Trends for Cosmetics Sector
- EU Cosmetics Regulation
- Main Steps to Meet Requirements of EU Cosmetics Regulation
- Sources of Information/Assistance

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EU Cosmetics Market Growth & Size

- ❖ EU is a top world market for cosmetics with a market size almost as **large as the U.S. and Japanese markets** combined – estimated to be worth almost **67 billion € in 2010**.
- ❖ The cosmetics sector is particularly attractive to U.S. exporters due to the **low import tariffs in the EU. U.S. cosmetics exports to the EU totalled roughly \$1.76 billion between 2010-2012**.
- ❖ Largest markets in the EU are Germany, France, the UK, Italy and Spain; but the greatest growth is seen in Eastern and Central Europe where personal care products grew by **58 percent in 2004-2009**.
- ❖ The market for “**natural**” products is the strongest, however, in Germany and France, with annual growth in this market sector as high as **30 percent in recent years**.

EU Regulation of Cosmetics

On July 11, 2013, the EU Cosmetics Regulation, EU 1223/2009, entered into force replacing the EU Cosmetics Directive which had been in place since the 1970s.

Why The Change: Greater Clarity and Harmonization

1. Clarified definition of cosmetic products
2. Better defined responsibilities -- manufacturer, importer, *responsible person*, distributor
3. Formalized contents of the *Product Information File (PIF)*
4. Outlined specific requirements and definitions for use of nanomaterials
5. Harmonized EU-wide surveillance system
6. Established Criteria for Product Claims (performance)

EU Definition of Cosmetics

- ❖ **EU Definition** -- “any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours”
- ❖ Products covered include not only traditional cosmetic products such as perfumes, fragrances and make-up, but also **personal care products** (i.e. lotions, skin products, soaps, facemasks, toiletries, bath products, deodorants, hair care products and **sunscreens**).
- ❖ This definition is **much broader than U.S. definition** and can make it difficult to determine appropriate classification of a given product as a cosmetic, medicine or biocide. EU provides guidance to assist in classifying “borderline” products.

Exporting Cosmetics to the EU

Main Requirements

All cosmetic and personal care products **may be candidates for being freely marketed within the EU provided they meet all 5 following conditions:**

1. are considered a cosmetic by the EU and that ingredient is **not subject to a prohibition or a ban** – see Annexes to EU Cosmetics Regulation & that the finished product and ingredients have not been tested on animals.
2. are subject to the oversight of a **Responsible Person**
3. are supported by a **Product Information File (PIF)**
4. have been notified on the **Cosmetic Products Notification Portal (CPNP)**
5. have the correct labeling and product (performance) claim criteria

EU Cosmetic Regulation's Responsible Person

- ❖ The Cosmetics Regulation requires that non-EU based exporters of cosmetic products retain a **Responsible Person**.
- ❖ The primary role of the **Responsible Person** is to certify that the exported products are safe, meet all the legal requirements for being placed on the EU market and maintain a copy of the PIF should any questions arise about the safety of a product or compliance.
- ❖ Additionally, only the Responsible Person can submit the notification dossier on the **Cosmetic Products Notification Portal (CPNP)**

EU Product Information File (PIF)

The **PIF** consists of the following elements:

- ❖ A description of the cosmetic product;
- ❖ A cosmetic product safety report (Note: Annex I of the Cosmetics Regulation sets out the requirements of the product safety report.);
- ❖ A description of the method of manufacturing and a statement on compliance with good manufacturing practice;
- ❖ Where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product; and,
- ❖ Data on any animal testing performed relating to the development, safety evaluation of the product, or its ingredients regardless of where such tests occurred.

Cosmetic Products Notification Portal (CPNP)

Informs the EU about:

1. the type of product(s) that the company is placing on the EU market;
2. the identity and contact information of the Responsible Person;
3. The country of origin;
4. The Member State where the product will be placed on the market;
5. Information about the presence of any substances contained in a nano form (scale from 1 to 100 nm);
6. The frame formulation of the product.

Labeling of Cosmetics in EU

- ❖ The EU Cosmetics Regulation contains special **labeling rules** applicable to cosmetic and personal care products such as instructions for the products use, including any relevant precautions; batch number or other reference for identifying the goods; a statement of the function of the product list of ingredients contained in the cosmetic product

However, it does not require the affixation of a CE mark.

Rather, the Regulation requires the following be “indelible, easily legible and visible” on the container and packaging:

- ✧ the name and address of the Responsible Person;
- ✧ the nominal content at the time of packaging (by weight or by volume) expressed in metric units (Dual labeling is permitted.)

Claims -- EU's “Common Criteria”

1. Require that **explicit and implicit claims are supported by adequate and verifiable evidence**;
2. **Prohibit** claims that indicate that a cosmetic product has been authorized or approved by a competent authority within the EU;
3. Prevent the **use of claims that attribute specific characteristics to a cosmetic product if similar cosmetic products** possess the same characteristics or if a specific benefit is in mere compliance with minimal legal requirements;
4. Require that claims do **not create confusion with competitor products, and do not denigrate competitors or ingredients legally used**.
5. The responsibility for ensuring that a company's claims comply with the common criteria is placed on the legal or natural person designated as the **‘responsible person’** for the cosmetic product concerned within the EU.

Resources

1. U.S. Commercial Service

- http://export.gov/europeanunion/accessingeumarketsinkeyindustrysectors/eg_eu_044318.asp

2. European Commission Main Website With Links to Regulation, CPNP portal, etc.

- http://ec.europa.eu/consumers/consumers_safety/cosmetics/index_en.htm
- EU Cosmetics Regulation
http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm

3. Industry Associations

- Cosmetics Europe
- <https://www.cosmeticseurope.eu>
- Independent Cosmetic Manufacturers and Distributors (ICMAD)
- <http://www.icmad.org>
- Personal Care Products Council (PCPC)
- <http://www.personalcarecouncil.org>

Follow Up Information/Contact

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